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To:	International Biocontrol Manufacturers Association AISBL ("IBMA")
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Date:	19 February 2025

A legal pathway to facilitate and accelerate the placing of biocontrol products on the EU market

On 24 January 2025, IBMA published a position paper outlining both immediate and mid-term solutions to accelerate biocontrol in the EU. The **immediate solution** consists of making targeted amendments to Regulation (EC) No 1107/2009[1] to adapt the existing approval and authorisation system to the particularities and needs of biological control.

We consider that such **targeted amendments to Regulation (EC) No 1107/2009 are legally possible**, in line with the spirit and purposes of Regulation (EC) No 1107/2009 and consistent with previous precedents and policy objectives in the EU. In fact, this seems to be the approach taken by the EU institutions lately, as reflected in the previous SUR Proposal or in other relevant areas such as biostimulants, the CLP amendment or the REACH amendment proposal. All this, in order to tackle the rigidity of existing legal procedures, to adapt them to new scientific developments and facilitate the arrival of more sustainable products. There is therefore a clear awareness among industry and public authorities of the urgent need to facilitate the introduction of biological plant protection products and more sustainable innovations in the EU.

The **purpose of this legal memo** is to provide the legal and procedural basis under which the targeted amendments proposed by IBMA could be adopted in order to allow for an authorisation and approval system more tailored to the circumstances and specific profile of biocontrol products, until a new independent regulatory framework for biocontrol is adopted.

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

Table of Contents

1. Make targeted amendments to essential aspects of Regulation (EC) No 1107/2009

The main **targeted amendments** proposed by IBMA can be summarised as follows[2]:

- A harmonised definition of biocontrol.
- Re-instatement of provisional authorisations for biocontrol.
- No renewal requirement for biological active substances and Plant protection products (PPPs) unless new scientific and technical knowledge indicates a necessity to re-review the substance or product.
- Facilitate label expansion for biocontrol plant protection products.

These targeted amendments to Regulation (EC) No 1107/2009 are in line with the amendments proposed by the EU Commission[3] . They will help to streamline and accelerate the placing on the market of biological control products in the EU, as well as to establish more efficient and pragmatic regulatory pathways, ensuring timely access to innovative, sustainable alternatives while maintaining high standards of safety and efficacy.

2. Legal basis and legislative procedure to make the amendments possible

The most appropriate legislative procedure to adopt all the targeted amendments is the **ordinary legislative procedure** due to the reasons explained below.

Firstly, some of the targeted amendments proposed by IBMA may be considered to affect **essential aspects** of Regulation (EC) No 1107/2009. These essential amendments must be adopted through the ordinary legislative procedure. The legal basis to adopt the amendments to essential aspects is set out in the EU treaties themselves.

- Article 114(1) of the TFEU states that in order to achieve the objectives laid down in Article 26 (Internal market), the European Parliament and Council -after consulting the Economic and Social Committee- shall adopt measures aimed at harmonizing Member States' laws to ensure the proper functioning of the internal market, with the European Parliament and the Council acting under the ordinary legislative procedure.

Secondly, the adoption of the targeted amendments via the ordinary legislative procedure is in fact the legal mechanism used to adopt similar amendments in other related areas:

- The recent **revision of CLP Regulation**[4] is one of the examples of the amendment of essential aspects of an EU Regulation via the ordinary legislative procedure and in accordance with Article 114 TFEU. This amendment was published in the EU Official Journal, on 20 November 2024[5].

- The ongoing **revision of REACH**[6] is as well intended to be subject to targeted amendments on essential aspects, in accordance with Article 114 TFEU, as announced by the European

[2] Position Paper: "Accelerate biocontrol to ensure farmers' livelihoods and Europe's competitive edge", International Biocontrol manufacturers association (IBMA), 2024, available at https://ibma-global.org/wp-content/uploads/2024/12/20250121_IBMA_PositionPaper-EnablingBiocontrol_Spread.pdf

[3] Page 133 of Commission Response to Council Decision (EU) 2022/2572 of 19 December 2022 requesting that the Commission submit a study complementing the impact assessment of the proposal for a regulation of the European Parliament and of the Council on the sustainable use of plant protection products and amending Regulation (EU) 2021/2115, available at https://food.ec.europa.eu/system/files/2023-07/pesticides_sup_comm-response_2022-2572_en.pdf

[4] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

[5] Regulation (EU) 2024/2865 of the European Parliament and of the Council of 23 October 2024 amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

[6] Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

Commission in its Inception Impact Assessment of the Revision of EU legislation on REACH[7].This revision will introduce amendments with a similar objective to the targeted amendments explained in Section 1 of this document, i.e. to address "heavy and inflexible authorisation procedures" or "complex and insufficient evaluation of registration dossiers and substances" as stated in the Inception Impact Assessment[8].

i. The amendments are legally possible through the ordinary legislative procedure.

The procedure for adopting the targeted amendments to Regulation (EC) No 1107/2009 would be the **ordinary legislative procedure** set out in Article 289 TFEU and further developed in Article 294 TFEU. This procedure begins with a legislative proposal prepared by the European Commission, following the discussion of the proposal and possible amendments by the European Parliament ("EP") and the Council as co-legislators.

The procedure can be summarised as follows:

- Legislative proposal by the European Commission and public consultation.
- Submission of proposal and accompanying documents to the EP and Council.
- EP adopts its position by amending or approving the proposal.
- Council adopts its position by approving EP's position or amending it.
- If Council approves EP's position, the legislative act is adopted at first reading.
- If Council does not approve EP's position, there can be a second or third reading phases.

Legal acts following the ordinary legislative procedure are normally **adopted within 17 months** in first reading, according to the statistical data of the European Parliamentary Research Service[9]. However, according to the legal deadlines established in Article 294 of the TFEU, the ordinary legislative procedure can take between 2-3 years to complete in some cases.

The decision to adopt the proposal is taken in the EP by simple majority and in the Council by qualified majority[10]. The adoption of the position by the Council shall be justified, informing the European Parliament fully of the reasons which led it to adopt its position at first reading.

During the reading phase, the EP and the Council **should not address other aspects or areas that deviate from or may distort** the core and genuine objective of the legislative proposal, which in this case would be facilitating and accelerating the placing on the market of biocontrol means in the EU[11].

ii. The amendments are in line with the spirit and purposes of Regulation (EC) No 1107/2009.

The targeted amendments listed in Section 1 are not only legally possible according to the rules of legislative procedure, but also in line with the spirit and purposes of Regulation (EC) No 1107/2009 by enhancing its objectives, as explained below.

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[7] Page 2 of the Inception Impact Assessment of the Revision of EU legislation on registration, evaluation, authorisation and restriction of chemicals – Available at https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment_en

[8] *Ibid.*

[9] Source: European Parliament Research Service – Available at https://epthinktank.eu/2024/06/04/european-parliament-facts-and-figures/ep-facts-and-figures-fig-19/

[10] Page 34 and 39 of the Handbook on the Ordinary Legislative Procedure of the European Parliament – Available at https://www.europarl.europa.eu/cmsdata/292561/OLP_Handbook_Dec2024_EN.pdf

[11] Judgement of 14 April 2015, Council v European Commission, C-409/13, EU:C:2015:217, para. 83: "It must be accepted that, where an amendment planned by the Parliament and the Council distorts the proposal for a legislative act in a manner which prevents achievement of the objectives pursued by the proposal and which, therefore, deprives it of its raison d'être, the Commission is entitled to withdraw it. It may, however, do so only after having due regard, in the spirit of sincere cooperation which, pursuant to Article 13(2) TEU, must govern relations between EU institutions in the context of the ordinary legislative procedure (see, to this effect, judgment in Parliament v Council, C-65/93, EU:C:1995:91, paragraph 23), to the concerns of the Parliament and the Council underlying their intention to amend that proposal."

One of the main objectives of Regulation (EC) No 1107/2009 is to regularly examine plant protection products and its substances with the aim of **replacing them by non-chemical control** or other prevention methods:

- Recital 19 of Regulation (EC) No 1107/2009 states "*Some active substances with certain properties should be identified at Community level as candidates for substitution. Member States should regularly examine plant protection products containing such active substances with the aim of replacing them by plant protection products containing active substances which require less risk mitigation or by non-chemical control or prevention methods*".

- Recital 35 of Regulation (EC) No 1107/2009 emphasises the same principle "*To ensure a high level of protection of human and animal health and the environment, plant protection products should be used properly, in accordance with their authorisation, having regard to the principles of integrated pest management and giving priority to non-chemical and natural alternatives wherever possible*"

Both Regulation (EC) No 1107/2009 and Directive 2009/128/EC on sustainable use of pesticides[12] ("**SUD**") emphasizes the need to apply **Integrated pest management** and biocontrol has a key role in this strategy.

- Article 1 of SUD highlights "*This Directive establishes a framework to achieve a sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of integrated pest management and of alternative approaches or techniques such as non-chemical alternatives to pesticides*".

- Article 3(6) of SUD defines "integrated pest management" as "*careful consideration of all available plant protection methods and subsequent integration of appropriate measures that discourage the development of populations of harmful organisms and keep the use of plant protection products and other forms of intervention to levels that are economically and ecologically justified and reduce or minimise risks to human health and the environment. 'Integrated pest management' emphasises the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms*".

Moreover, the **key regulatory definitions** in Regulation (EC) No 1107/2009 were intended to comprise non-chemical substances and natural or more sustainable alternatives:

- Article 3(2) of Regulation (EC) No 1107/2009 defines "'substance" as: "*chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process".*

- Article 3(8) of Regulation (EC) No 1107/2009 defines "non-chemical-method" as: "*alternative methods to chemical pesticides for plant protection and pest management, based on agronomic techniques such as those referred to in point 1 of Annex III to Directive 2009/128/EC, or physical, mechanical or biological pest control methods*".

- Article 3(15) of Regulation (EC) No 1107/2009 defines "micro-organisms" as: "*any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material*". The definition of "micro-organisms" was included in the Regulation from the very beginning, reflecting the legislator's recognition of its relevance.

[12] Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides.

The inclusion of the amendments for biocontrol by amending an existing Regulation (i.e. Regulation EC (No) 1107/2009), would be in line with the principle of **efficiency and coherence** as stated in paragraph 22 of the Interinstitutional Agreement on Better Law-Making[13].

The **Proposal for a Regulation on Sustainable use of Pesticides** ("**SUR**") followed the approach outlined in this memo and included targeted amendments to essential aspects of Regulation EC (No) 1107/2009. One of the most significant targeted amendments suggested by the complementary Study to the Impact assessment accompanying the SUR[14] is the reintroduction of provisional authorisations for biocontrol products under Article 30 of the Regulation (EC) No 1107/2009.

The proposed targeted amendments would not undermine core legal principles such as the **principle of legal certainty and non-retroactivity of legal acts**, as the amendments would apply from the entry into force of that amending act. This includes the reactivation of provisional authorisations, which would apply to new situations arising from the date of entry into force of the amending regulation, thereby being consistent with the EU case law on the principle of non-retroactivity[15].

The adoption of the targeted amendments would be also in line with the **principle of equal treatment and non-discrimination**. The fact that the amendments would apply to biocontrol and not to other plant protection products is a measure justified under Article 36 TFEU, on grounds of protection of health and life of humans, animals or plants, since it would entail placing on the market sustainable plant protection products with a safer environmental and health risk profile.

iii. The amendments are consistent with previous precedents and policy objectives in the EU.

The **SUR** is the clearest recent example that these targeted amendments are possible:

- This proposal already contained some of these targeted amendments to essential aspects of Regulation EC (No) 1107/2009, such as definition of biocontrol, provisional authorisations or faster and simpler procedures for new and less harmful pesticides.

- The SUR embraced the idea outlined in this memo and was intended to follow the same legislative procedure to make it real, i.e. by adopting a regulation via ordinary legislative procedure which would make amendments to essential aspects of Regulation EC (No) 1107/2009. The strategy to amend the main body of the Regulation EC (No) 1107/2009 has been strongly encouraged by the EC and the European parliament's committees during the development and debates of the SUR. During such debates on the SUR, one recurring point of consensus emerged: the need to reduce pesticide use without compromising farmer's ability to sustain their production and, to this end, expediting access to alternative plant protection products such as biocontrol products.

- The reasons for the withdrawal of the SUR were mainly related to a disagreement with the proposed pesticide reduction objectives and were not related to targeted amendments for biocontrol.

[13] Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making, para 22: "In the context of the legislative cycle, evaluations of existing legislation and policy, based on efficiency, effectiveness, relevance, coherence and value added, should provide the basis for impact assessments of options for further action. To support these processes, the three Institutions agree to, as appropriate, establish reporting, monitoring and evaluation requirements in legislation, while avoiding overregulation and administrative burdens, in particular on Member States."

[14] Page 133 of Commission Response to Council Decision (EU) 2022/2572 of 19 December 2022 requesting that the Commission submit a study complementing the impact assessment of the proposal for a regulation of the European Parliament and of the Council on the sustainable use of plant protection products and amending Regulation (EU) 2021/2115, available at https://food.ec.europa.eu/system/files/2023-07/pesticides_sup_comm-response_2022-2572_en.pdf

[15] Judgement of 16 December 2010, Stichting Natuur en Milieu v CTB, C-266/09, EU:C:2010:779, para. 32; "As a matter of principle, a new rule of law applies from the entry into force of the act of which it forms part. While it does not apply to legal situations which have arisen and become definitive under the old law, it applies to their future effects, as well as to new legal situations (see, to that effect, Case C 428/08 Monsanto Technology [2010] ECR I 0000, paragraph 66). It is otherwise – subject to the principle of the non-retroactivity of legal acts – only if the new rule is accompanied by special provisions which specifically lay down its conditions of temporal application."

The targeted amendments are also in line with the **policy acts and documents** recently adopted by EU institutions to boost bioeconomy:

- The **Communication for a Sustainable Bioeconomy for Europe (Bioeconomy strategy)**[16] states that the EC and other institutions should support the EU industrial base through the development of innovative solutions for the production of new and sustainable bio-based products, particularly: (i) *Bio-based innovations including in farming, to develop new chemicals, products, processes and value chains for bio-based-markets in rural and coastal areas, with involvement and increased benefits for primary producers.*

- The **Staff Working Document of the Sustainable Bioeconomy for Europe**[17] and the Commission Expert Group for Bio-based Products[18] alerted that the lack of a Regulation for biocontrol solutions is a bottleneck for the bio-based industry: *"Therefore, there is still a need to Identify bottlenecks, enablers, and gaps that hamper the market uptake and industrial exploitation of bio-based innovations, including in relevant EU policy areas such as Research and Innovation, circular economy, environmental and human health protection, construction, textiles, plastics, waste, fertilisers, CAP, Industrial Policy, etc."*

- In the **Communication from the Commission ensuring resilient and sustainable use of EU's natural resources**[19], the Commission addressed those possible options for co-legislators regarding new biocontrol active substances in terms of reducing the approval procedure and less administrative burden.

- The **Strategic Dialogue on the future of EU agriculture** ensuring that the EU remains aligned with the goals of the EU Green Deal has been considered essential for the upcoming 2024-2029 mandate. This report recommends a "robust legal framework for biocontrol by 2025" and the Mission Letter of Commissioner Hansen includes implementation of the recommendations for the Strategic Dialogue, A key priority will be the implementation of a legal framework and at least two Implementation Dialogues per year with stakeholders to maintain realities on the ground. President Von Der Leyen has ordered to further develop the Bioeconomy Strategy, and a new European Biotechnology Act aimed at fostering the need for a regulatory environment that supports innovation to Commissioners Ms Roswall[20] and Mr Várhelyi[21].

- The **Work Programme 2025**[22] emphasises the need to simplify and streamline permitting and authorisation procedures and to ensure coherence of the regulatory framework in relevant sectors such as the biotechnology industry. The Work Programme includes the Bioeconomy Strategy as part of its simplification agenda (Annex I), which, as mentioned above, aims to promote all types of innovations and practices for sustainable food and farming systems, forestry and bio-based production, such as biological control.

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[16] Page 12 of European Commission: Directorate-General for Research and Innovation, A sustainable bioeconomy for Europe – Strengthening the connection between economy, society and the environment – Updated bioeconomy strategy, Publications Office, 2018, available at https://op.europa.eu/en/publication-detail/-/publication/edace3e3-e189-11e8-b690-01aa75ed71a1/

[17] *Ibid.* page 63.

[18] Page 1 of Commission Expert Group for Bio-based Products – Working Groupon Evaluation of the Implementation of the Lead Market Initiative for Bio-based Products' Priority Recommendations, Ref. Ares(2015)4468322 - 21/10/2015.

[19] Page 9 of Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the regions - Ensuring resilient and sustainable use of EU's natural resource, 2023, available at https://commission.europa.eu/document/download/a2a71c6d-1dee-41bb-b2ee-51c1cb35d3f4_en?filename=Communication%20on%20Sustainable%20Use%20of%20Natural%20Resources.pdf

[20] Source: Jessika Roswall's Mission Letter - https://commission.europa.eu/document/download/10a1fd18-2f1b-4363-828e-bb72851ffce1_en?filename=Mission%20letter%20-%20ROSWALL.pdf

[21] Source: Olivér Válheryi's Mission Letter - https://commission.europa.eu/document/download/b1817a1b-e62e-4949-bbb8-ebf29b54c8bd_en?filename=Mission%20letter%20-%20VARHELYI.pdf

[22] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions; Commission Work Programme 2025; Moving forward together: A Bolder, Simpler, Faster Union, available at: https://commission.europa.eu/document/download/f80922dd-932d-4c4a-a18c-d800837fbb23_en?filename=COM_2025_45_1_EN.pdf

The inclusion of a biocontrol definition and provisions facilitating the approval and authorisation of biocontrol by amending Regulation EC (No) 1107/2009 would help to achieve the above objectives more rapidly.

3. Legal options to adopt the amendments

The targeted amendments to Regulation (EC) No 1107/2009 can be adopted in two different ways: one option is adopting a specific amending regulation; the other option is to adopt a more general (omnibus) legislation amending at the same time several existing legal acts that are applicable to different sectors. The clearest example of the latter, the EU Biotechnology Act proposed by the European Commission, which we believe/could be the most appropriate and coherent way to adopt the targeted amendments.

i. Specific amending regulation

The targeted amendments could be adopted by a specific regulation intended only to modify Regulation (EC) No 1107/2009. All the targeted amendments can be made by a single "amending regulation" of the European Parliament and the Council under the ordinary legislative procedure. This is the approach that has been followed for the revision of the CLP Regulation or the ongoing revision of REACH, amongst others.

The European Commission published the Chemical Strategy for sustainability ("Strategy")[23], as part of the European Green Deal. The main objective of this Strategy is to protect citizens and the environment against hazardous chemicals and encourage innovation for the development of safe and sustainable chemicals. Under this Strategy, several Regulations such as the Cosmetic Regulation, CLP and REACH Regulation are being subject to a targeted revision based on Article 114 TFEU and the ordinary legislative procedure (same legal basis and procedure that we propose for the targeted amendment to Regulation (EC) No 1107/2009). These revisions and amendments have been made by means of separate independent regulations amending each existing act.

The Commission's Work Programme 2025 foresees the adoption of a targeted revision of REACH in Q4 2025 as part of the Clean Industrial Deal (Q1 2025). Similarly, a specific amending regulation on biocontrol could be adopted in 2025 to implement the targeted amendments under Regulation (EC) No 1107/2009 in order to simplify and streamline approvals and authorisations for biocontrol in line with the simplification agenda of the Work Programme and the objectives of the Bioeconomy Strategy included in Annex I of the Work Programme.

ii. EU Biotechnology Act

Alternatively, the EU Biotechnology Act also represents a coherent and fit-for-purpose way to introduce the targeted amendments to Regulation (EC) No 1107/2009, albeit not within the required 2025 timeline:

- The amendments are in line with the purpose of the EU Biotechnology Act. The launch of the EU Biotechnology Act reflects the Commission's initiative to reduce fragmentation, explore possible simplifications and shorten the time to market for biotechnological innovations[24].

- The adoption of these amendments would be quicker, as there is already common agreement and support by the biotech industry, authorities and the public on the need to promote and facilitate biotechnological innovations in the EU to respond to current environmental and public health challenges, which touches upon many important sectors (agriculture, food, pharmaceutical,

[23] Page 24 of Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions - Chemicals Strategy for Sustainability, 2020, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2020:667:FIN

[24] Page 20 of Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions - Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU, 2024, available at https://research-and-innovation.ec.europa.eu/document/download/47554adc-dffc-411b-8cd6-b52417514cb3_en

etc).[25]The European Commission is launching a study analysing how the legislation that applies to biotechnology and biomanufacturing could be further streamlined across EU policies exploring targeted simplifications to the regulatory framework, including for faster approval and bringing to the market. The foundations for a possible EU Biotechnology Act will start this year[26].

- The Commission Work Programme 2025 foresees the adoption of several omnibus regulations to simplify existing legislation. The Biotechnology Act is well placed to be one of these omnibus regulations to achieve the objectives of supporting and promoting innovations for sustainable food and farming systems and bio-based production, as set out in the Bioeconomy Strategy envisaged in Annex I of the Work Programme.

The legal basis and procedure to adopt the EU Biotechnology Act would be also the ordinary legislative procedure on the basis of Article 114 of the TFEU.

The EU Biotechnology Act could be used as an "**omnibus" cross-sectoral legislation** amending simultaneously several existing regulations that apply to different biotechnology sectors. All of this, with the main purpose of responding to the current needs and helping biotech companies in bringing innovative products to the market. The targeted amendments to Regulation (EC) No 1107/2009 would be included in the EU Biotechnology Act in a specific Section for biological plant protection products, which would coexist with other sections establishing similar amendments to the use of other biotechnologies that are relevant in other industries. This is in line with the main idea outlined by the European Commission in the Communication "Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU", where the EU Biotechnology Act strategy is mentioned. Examples of the industries and biotechnologies mentioned are for instance, (i) mRNA therapeutics, (ii) sustainable biomass, recycled waste and CO2 captured from biogenic sources for use as energy in the chemical manufacturing industry instead of fossil carbon or (iii) modified enzymes for use as a filtration system for clean water.[27]

The **Artificial Intelligence Act** ("**AI Act**") or Regulation (EU) 2024/1689[28] is a clear recent example of a similar "omnibus" legislation modifying several sectorial regulations to achieve a single purpose. This AI Act was also adopted throughout the ordinary legislative procedure and in accordance with Articles 114 and 16 of the TFEU. It establishes a horizontal, cross-sectoral legal framework to improve the functioning of the internal market and promote the deployment of human-centred and trustworthy artificial intelligence, while ensuring a high level of protection of health, safety and fundamental rights. It amends a total of nine sectoral regulations and directives, establishing harmonised rules for the placing of AI systems on the market and setting out specific legal requirements.[29]

The **key advantage** of adopting the targeted amendments through the EU Biotechnology Act lies on the strength and broad impact of this legislative initiative. By comprising multiple industries, the Biotechnology Act will create a robust regulatory framework (just as the AI Act has done) to ensure that biotechnology innovations are accessible in the EU in a shorter timeframe

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[25] *Ibid*. pages 4-5.

[26] *Ibid*. pages 20.

[27] *Ibid*. pages 4-5.

[28] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act).

[29] *Ibid*. Art. 1